Chairman Frank Pallone, Jr.
Health Subcommittee Hearing

Discussion Drafts Concerning Prescription Drug User Fee Act Reauthorization, Medical Device User Fee and Modernization Act Reauthorization, Drug Safety, and Certain Pediatric Pharmaceutical and Device Legislation

Opening Statement

June 12, 2007

Good morning. Today the Subcommittee is meeting to hear testimony about discussion drafts concerning the Prescription Drug User Fee Act Reauthorization, Medical Device User Fee and Modernization Act Reauthorization, Drug Safety, and several proposals to encourage more research in to the appropriate use of drugs and devices in pediatric populations.

I will note, as a matter of process, each of these issues has had its own hearing in the Subcommittee over the course of the past six weeks. We have worked very hard to cover a lot of ground. I want to thank all the Subcommittee members for their participation in these hearings, and I welcome comments and suggestions on these discussion drafts as we continue to move forward.

I will also note that while we did have a hearing regarding follow-on biologics, I did not include a proposal in last week's drafts that would address this issue. I want to stress that this issue is of vital importance and it lack of inclusion should not be viewed as a signal to anyone that the door is closed on this very important

topic. I am still very interested in developing a consensus on this issue and hope to do so in the near future.

Let me just say a few words about each of the discussion drafts that were circulated last week. The proposal to reauthorize the Prescription Drug User Fee Act (PDUFA) is largely based on the agreement between the FDA and the industry, with a few changes. First, and foremost, an additional $225 million in user fees is authorized in the discussion draft. These new fees would be dedicated to post-market safety activities and would build upon the $29 million in additional fees already included in the administration's proposal for post-market safety activities.

We also include a provision that would require more transparency in the next PDUFA process by allowing a consumer or patient group to participate in the negotiations between the Food and Drug Administration and the pharmaceutical industry.

Like the PDUFA proposal, the discussion draft to reauthorize the Medical Device User Fee and Modernization Act (MDFUMA) is also largely based on the proposed agreement between the FDA and the medical device industry, with some modifications. Undoubtedly, the most controversial change is to eliminate the changes to the third party inspection program.

I realize that the medical device industry has deep concerns about this provision over the last week. However, I have not been convinced that these changes are necessary in order to improve participation in the program. No one has been able to show me how or why the policies we are changing act as significant barriers to participation. Finally, I have a philosophical problem with the idea of liberalizing a program that is designed to privatize a core function of a government regulatory agency. Other key changes to the MDUFMA proposal include a study of the 510(k) process and an authorization of appropriations for post-market activities.

We also circulated two draft proposals to reauthorize the Best Pharmaceuticals for Children's Act (BPCA) and the Pediatric Research Equity Act (PREA) which are designed to provide necessary research on the appropriate use of prescription drugs in pediatric populations. While these drafts make a number of changes to the program, the two largest changes are eliminating the sunset provision associated within PREA and including an exclusivity adjustment under BPCA.

Also included among these drafts are a proposal supported by Representatives Markey and Rogers to encourage the development of devices to be used in pediatric populations.

Finally, we included a number of proposals that would improve our drug safety system. I realize that the drug safety provisions will be the most contentious. We

saw how contested this debate was in the Senate and it is my hope that we can avoid having a repeat performance in this Subcommittee. However, it is very clear that there are gaping holes in the current system and the public has lost a great amount of confidence in FDA's ability to protect them from potentially harmful drugs. We must work diligently to strengthen our nation’s drug safety system and restore the public's trust in FDA.

At the heart of our drug safety proposal is the requirement that all new drugs include a risk evaluation and mitigation strategy, which outline the conditions that need to be put in place to ensure that FDA has the tools necessary to protect consumers from unknown risks associated with a new drug. I realize that not everyone is going to agree with the REMS strategy or how we are proposing to implement it. The direct to consumer advertising provisions included in the REMS have already caused great anxiety among stakeholders and members. I am open to hearing all these concerns.

Other provisions included in the drug safety drafts are a new clinical trials registry and results database, which are designed to give patient and providers greater access to the information they need to determine the most appropriate and safest course of treatment. There are also new conflict of interest standards that are designed to ensure that FDA’s Advisory Committees remain impartial and provide the best possible advice when it comes to critical issues that impact the public health.

These are the major provisions of the draft we circulated last week and which we will hear more about today. Again, I thank all the Subcommittee's members for their participation in the hearings we had and I am looking forward to getting your feedback today.

I would like to also welcome our witnesses here today. We are very eager to hear from you and hear your opinions and whatever suggestions you may have. I now will recognize my good friend Mr. Deal from Georgia for five minutes for the purpose of making an opening statement.